

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MOLECULAR LOOP BIOSCIENCES, INC.,)	
)	
Plaintiff,)	
)	C.A. No. 24-680-RGA-SRF
v.)	
)	JURY TRIAL DEMANDED
ILLUMINA, INC. and)	
VERINATA HEALTH, INC.,)	
)	
Defendants.)	
)	

**PLAINTIFF’S REPLY BRIEF IN SUPPORT OF MOTION TO DISMISS
COUNTERCLAIMS AND STRIKE AFFIRMATIVE DEFENSES OF
INEQUITABLE CONDUCT AND PROSECUTION LACHES**

Dated: December 18, 2024

OF COUNSEL:

Brian D. Matty
Deborah J. Mariottini
Ashley DaBiere
Kevin Goon
DESMARAIS LLP
230 Park Avenue
New York, NY 10169
Tel: 212-351-3400
Tel: 415-573-1900

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
FARNAN LLP
919 N. Market St., 12th Floor
Wilmington, DE 19801
(302) 777-0300
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

*Attorneys for Molecular Loop Biosciences,
Inc.*

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Exhibits attached to the Declaration of Ashley S. DaBiere in Support of Plaintiff's Motion to Dismiss Counterclaims and Strike Affirmative Defenses of Inequitable Conduct and Prosecution Laches dated November 1, 2024 (D.I. 23):

Exhibit	Description
1	United States Patent 9,163,281, issued on October 20, 2015 (with highlighting added)
2	United States Patent 11,041,851, issued on June 22, 2021 (with highlighting added)
3	Office Action filed on September 20, 2017, under United States Patent Application 14/854,629 (excerpted and with highlighting added)
4	Response and Remarks to Office Action, under United States Patent Application 14/854,629, dated March 20, 2018 (excerpted and with highlighting added)
5	Amendment and Response to Notice of Informal or Non-Response CPA Amendment, under United States Patent Application 14/854,629, dated January 15, 2021 (excerpted and with highlighting added)
6	Applicant-Initiated Interview Summary filed on November 18, 2020, under United States Patent Application 15/231,687 (excerpted and with highlighting added)
7	Applicant-Initiated Interview Summary filed on December 19, 2018, under United States Patent Application 15/231,687 (excerpted and with highlighting added)
8	Applicant-Initiated Interview Summary filed on April 21, 2021, under United States Patent Application 17/149,504 (excerpted and with highlighting added)
9	Amendment and Response to Non-Final Office Action, dated April 13, 2021, under United States Patent Application 17/149,504 (excerpted and with highlighting added)
10	Notice of Allowance and Fee(s) Due dated on April 27, 2021, under United States Patent Application 17/149,504 (excerpted and with highlighting added)
11	Recission of Previous Nonpublication Request, dated June 21, 2024, under United States Patent Application 18/483,878 (with highlighting added)
12	Communication Regarding Recission of Previous Nonpublication Request, filed on June 25, 2024, under United States Patent Application 18/483,878

	(with highlighting added)
13	United States Patent Publication 2024/0327908 A1, published on October 3, 2024 (excerpted and with highlighting added)
14	Filing Receipt filed on August 23, 2016, under United States Patent Application 15/231,687 (excerpted and with highlighting added)
15	Filing Receipt filed on December 1, 2020, under United States Patent Application 16/952,764 (excerpted and with highlighting added)
16	Application Data Sheet regarding United States Patent Application 16/952,764, filed on November 19, 2020 (with highlighting added)
17	Appeal Brief filed on October 8, 2021, under United States Patent Application 16/952,764 (excerpted and with highlighting added)
18	Application Data Sheet regarding United States Patent Application 15/231,687, filed on August 8, 2016 (with highlighting added)

Exhibits attached to the Continued Declaration of Ashley S. DaBiere in Support of Plaintiff's Motion to Dismiss Counterclaims and Strike Affirmative Defenses of Inequitable Conduct and Prosecution Laches dated December 18, 2024 (filed herewith):

Exhibit	Description
19	Defendant Genosity, Inc.'s Answer and Counterclaims to Plaintiff's Complaint for Patent Infringement (D.I. 9) from <i>Natera, Inc. v. Genosity, Inc.</i> , C.A. No. 20-cv-1352-LPS (D. Del. Feb. 15, 2021) (excerpted and with highlighting added)

Defendants accuse Molecular Loop of quibbling with “merits” at the pleading stage (D.I. 28 (“Opp.”) at 1), but even in the light most favorable to Defendants, their pleadings fail to plausibly allege either prosecution laches or inequitable conduct as a matter of law. Defendants argue that their allegations should survive because they are lengthy, but under FRCP 9(b) they must plead *with particularity* facts to support their claim. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328-29 (Fed. Cir. 2009). Defendants’ allegations might span 190 paragraphs, as they repeatedly boast, but those paragraphs fail as a matter of law to meet the pleading standards.

First, Defendants fail to plead prosecution laches because Defendants’ factual allegations describe only garden variety patent prosecution. Defendants baldly ascribe malicious intent to the inventors and prosecuting attorneys, but that cannot elevate actions to egregious misuse of the patent system for prosecution laches. Defendants also have not sufficiently pled intervening rights.

Second, Defendants’ inequitable conduct allegations fall far below the Rule 9(b) standard. For the ’852 and ’200 Patent patents, Defendants do not allege any false statement and all but admit they cannot plead non-cumulativeness. For the ’730 Patent, Defendants label a nonpublication as “egregious misconduct” to dodge the materiality requirement. But Defendants pled no egregious act and cannot tie nonpublication requests to patentability at all. And for all Asserted Patents, Defendants fail to plead any facts even hinting at an intent to deceive the PTO.

I. DEFENDANTS CANNOT PLEAD PROSECUTION LACHES.

In over 70 paragraphs of allegations and 11 pages of briefing on laches, Defendants *never* even purport to allege that any prosecution delay “constitutes an *egregious misuse of the statutory patent system* under the totality of the circumstances.” *Cancer Rsch. Tech. Ltd. v. Barr Lab’ys, Inc.*, 625 F.3d 724, 728 (Fed. Cir. 2010). Without egregious misuse, Defendants’ pleadings fail as a matter of law even under their version of events. *See id.* Defendants do not dispute that Molecular Loop’s application filings were expressly allowed by statute. They instead argue that Molecular

Loop should have moved more expeditiously and should have filed applications in parallel. Opp. at 6. But the Supreme Court has explained that “laches . . . cannot be invoked to bar legal relief in the face of a statute of limitations enacted by Congress.” *SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 580 U.S. 328, 331 (2017). Defendants’ allegations fail to establish any plausible theory of prosecution laches and should be dismissed and stricken.

A. Defendants Cannot Sufficiently Plead Unreasonable Or Unexplained Delay.

1. Defendants’ Allegations For The ’852 And ’200 Patents Fail.

For the ’852 and ’200 Patents, Defendants’ pleadings reflect only standard prosecution mixed with self-evidently false allegations. Defendants acknowledge that they allege delay merely because “[t]he application that led to the ’852 Patent was not filed until January 14, 2021, over 10 years after its earliest effective filing date based on the 2010 provisional application, and over 5 years after issuance of the first filed patent in its family.” Opp. at 4 (*citing* CC ¶ 27). But the prosecution histories show only the mundane course of prosecution: one original patent and three divisional and/or continuation patents filed and obtained successively as applications issued.

Defendants take issue with the length of prosecution, but the delay element of prosecution laches “is not simply a time-counting exercise.” *Wirtgen Am., Inc. v. Caterpillar, Inc.*, 2024 WL 3888116, at *4 (D. Del. Aug. 21, 2024).¹ Defendants argue that Molecular Loop did not immediately file a divisional application once the examiner required a claim election (*see* Opp. at 6), but those allegations are unpled and should be disregarded. *See Equil IP Holdings LLC, v. Akami Techs., Inc.*, 722 F.Supp.3d 450, 454 (D. Del. 2024). Moreover, the Federal Circuit has held that “it cannot, without more, be an abuse of the system to file divisional applications on various aspects that the PTO has considered to be separate and distinct from each other. . . . *That is so even*

¹ Defendants dismiss established law from summary judgment opinions. *See* Opp. at 4-5 n. 1. But if the best “delay” story Defendants can muster fails as a matter of the law, their pleadings fail.

when one defers the filing of a divisional application until just before the issuance of the parent application.” *Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005), *amended sub nom*, 429 F.3d 1051 (Fed. Cir. 2005). Defendants did not allege any other delay. They thus fail to raise any reasonable inference of unreasonable and unexplained delay that could plausibly amount to egregious misuse of the patent system.

Defendants argue that *Symbol*—the standard-setting case establishing the propriety of Molecular Loop’s actions—supports Defendants by arguing that they pled “more” than just serial prosecution. Opp. at 6. But tellingly, Defendants do not attempt to analogize this case to *Symbol*, because the allegations here do not come close to *Symbol*. The *Symbol* patentee prosecuted *hundreds of new claims* around *thirty years after its original application* in a patent family that was a poster child for so-called pre-GATT “submarine patent” problems. *See Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 301 F.Supp.2d 1147, 1156 (D. Nev. 2004). The *Symbol* Court noted that the patents occupied “the top thirteen positions for the longest prosecutions” *from 1914 to 2001*. *Id.* Those facts do not remotely resemble Defendants’ allegations. The *Symbol* problem was that the pre-GATT Lemelson patents were manipulated to obtain claims that would not expire until “*fifty-five years after the 1956 application was filed*[.]” *Id.* That issue, where delay extended the lives of patents, is nothing like the post-GATT patents here, where “patent terms are now measured from effective filing date[.]” *Cancer Rsch.*, 625 F.3d at 732. Molecular Loop’s sequential filings actually *reduced* the later patents’ terms, the opposite of the *Symbol* patents.

The “more” that Defendants claim they alleged are prejudice allegations now refashioned as unreasonable delay. And even with those allegations, Defendants’ pleadings fail because they allege only facts that are facially incorrect and otherwise irrelevant. Defendants sidestep their facially incorrect allegations as “improper merits based argument,” ignoring that “a court need not

accept as true allegations that contradict matters properly subject to judicial notice or by exhibit,” *Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 913 (Fed. Cir. 2017), and may consider file history as “a matter of public record,” *Allergan USA, Inc. v. Prolenium US Inc.*, 2019 WL 7298569, at *6 (D. Del. Dec. 30, 2019), *adopted*, 2020 WL 409684 (D. Del. Jan. 24, 2020). The Court is not required to accept Defendants’ facially inaccurate allegations. D.I. 22 (“Mot.”) at 4-5. Defendants thus fail to plead anything “more” than normal prosecution of four related patents.

Defendants misunderstand their pleading failures. While it is inaccurate to allege that Molecular Loop copied its inventions, that it copied text from undisclosed references,² and that it tried to pass off others’ inventions as their own, the reason Defendants’ pleadings fail is because all of those nefarious accusations they lob at Molecular Loop have nothing to do with delaying prosecution. District courts have dismissed prosecution laches claims where defendants’ pleadings of unreasonableness related to patent substance untethered to actual delay. *See, e.g., Kawasaki v. Rorze Corp.*, 2024 WL 2984991, at *7 (N.D. Cal. June 14, 2024) (dismissing prosecution laches allegations that patentee “intentionally strung out serial prosecution as to attempt to [] read upon the activities of its competitors,” because the alleged unreasonableness related to patent substance instead of any purported delay effect).

Defendants also rely on *Natera, Inc. v. Genosity Inc.* to argue Molecular Loop “improperly sought to delay competition ... by pursuing patent claims it did not invent” (Opp. at 4), but the circumstances there were entirely different. The *Natera* patent followed “16 provisional []

² Defendants inexplicably insist that Molecular Loop copied Steinmann WO2010/056728 without disclosure (Opp. at 5-6) when the counterpart Steinmann US2011/0301042, ***which is cited in the Asserted Patents, has the exact same language that was incorporated.*** Compare WO2010/056728 (D.I. 13, Ex. A) at 5, *with* US2011/0301042, ¶ 18. Unreasonable delay cannot be inferred from nonsensical allegations that Molecular Loop, rather than incorporating the cited reference, copied from and “did not disclose” the counterpart with the same exact disclosure.

applications and 11 [family] applications, almost half of which were abandoned.” Ex. 19 at 22. Here, by contrast, the four applications in the ’852 and ’200 Patent family *all issued as patents*. Moreover, Genosity alleged that Natera filed an application after a Natera “senior executive[] left Natera, began working for ArcherDX, *gained access to confidential information* relating to ArcherDX’s technology and then returned to Natera.” *Id.* at 24. Defendants alleged nothing of the sort. That the pleadings survived in *Natera* does nothing to save Defendants’ allegations here.

2. Defendants’ Allegations For The ’730 Patent Fail.

Rather than meaningfully respond on the ’730 Patent, Defendants dismiss Molecular Loop’s motion as merits based. Opp. at 8. But again, judicial notice of the prosecution history is appropriate. *Sound View Innovations, LLC v. Facebook, Inc.*, 204 F.Supp.3d 655, 658 (D. Del. 2016). The prosecution history shows that Molecular Loop filed the ’730 Patent immediately following the *examiner’s request* that it do so. Ex. 6 at 1. There was no delay that could have been unreasonable or unexplained. And Defendants’ argument that a nonpublication request (addressed below) somehow creates unreasonable delay cannot create a plausible inference of prosecution laches because Defendants have *no explanation* how such a request could delay prosecution at all.

B. Defendants Cannot Sufficiently Plead Prejudice.

Defendants argue that they need only “show that the holder of intervening rights would have *either* done something differently *or* experienced a change in economic position as a result of the alleged delay in issuance of the patent-in-suit.” Opp. at 9 (emphasis in original). Defendants argue “[i]t is an either-or.” *Id.* But Defendants pled *neither* and cannot plead prejudice.

Defendants now apparently concede that their alleged “prejudice” is irrelevant, focusing only on their allegation that “all three categories of accused products were developed and launched in 2012, 2017, and 2018,” during Defendants’ alleged delay. Opp. at 10. This Court has already determined that pleading investments in the products does not amount to an allegation that

Defendants “invested in, worked on, or used the claimed technology.” *See Allergan Holdings Unlimited Co. v. MSN Lab’ys Priv. Ltd.*, 2024 WL 3444368, at *3 (D. Del. July 17, 2024). Defendants attempt to distinguish the issue in *Allergan* as being “a mismatch between the alleged investment of time and resources into commercializing generic versions of a particular drug and the claimed invention (a particular method of treatment)” (Opp. at 10), but Defendants ignore that their allegations have the same issue as those in *Allergan*; the Asserted Patents claim *methods*. Accordingly, by only alleging that the accused products, and not the claimed technologies, were developed during the purported delay, Defendants have not sufficiently alleged prejudice.

II. DEFENDANTS CANNOT PLEAD INEQUITABLE CONDUCT.

A. Defendants’ Allegations For the ’852 And ’200 Patents Fail.

1. Defendants Fail To Allege Unmistakably False Statements.

Defendants argue that they adequately pled inequitable conduct simply because they say Molecular Loop’s arguments were false. Opp. at 12-13. But a belief of falsity is not enough to sustain inequitable conduct claims. *See ArrMaz Products Inc. v. Rieth-Riley Construction Co. Inc.*, 2024 WL 3043317, at *6 (N.D. Ind. Jun 18, 2024) (finding belief of specific intent insufficient without specific facts upon which to reasonably base that belief). In defending their *ipse dixit* approach to pleading, Defendants argue both that materiality is irrelevant because “knowingly false statements can constitute ‘egregious misconduct’” and that intent is irrelevant to whether conduct was “egregious.” *See* Opp. at 12. Defendants’ position would essentially allow inequitable conduct into every patent case, as long as defendants branded any attempt to advocate for claim allowance as “false.” Defendants’ version of the law and pleading standard cannot be correct.

To the contrary, Defendants must plausibly allege unmistakably false statements, which they did not. Defendants argue that statements that Parmeswaran was “directed to overcoming a problem unique to pyrosequencing” and “addresses ‘limitations inherent in pyrosequencing’” were

unmistakably false because Fuller “showed that the applicants and their attorney clearly ‘understood that Parameswaran is *not* limited to bead-based pyrosequencing.’” Opp. at 12. But Defendants have not put forth a contradiction. Neither statement says Parameswaran is limited to bead-based pyrosequencing.³ Defendants even admit that far from the words of Fuller revealing “unmistakably false” statements, their characterization is only an “interpretation.” Opp. at 13.

As explained, Defendants’ approach was rejected in *Prollenium*. See Mot. at 13. Defendants argue that rather than mischaracterize, they “accurately and directly quote from Fuller itself.” Opp. at 13. That is false. Defendants allege contradictions from their own interpretations, not quotes. See CC, ¶ 82 (attributing statements to applicants but not quoting), ¶ 94 (characterizing but not quoting Fuller), ¶¶ 95-96 (arguing that applicants said Parameswaran had “no application to ‘Illumina-type clusters’” and alleging applicants’ understanding of Parameswaran from Fuller without quoting Fuller, Parameswaran, or applicants). As in *Prollenium*, Defendants’ casting of statements as opposite when they are plainly not cannot sustain inequitable conduct allegations.

2. Defendants Cannot Plead But-For Materiality Of Applicant Statements.

Defendants assert that alleging “[b]ut-for the Applicants’ false statements distinguishing Parameswaran, the claims of the ’852 Patent would not have issued” sufficiently pleads but-for materiality. Opp. at 14. But Defendants cannot sustain their claim on that bald assertion. See *TwinStrand Biosciences, Inc. v. Guardant Health, Inc.*, 2023 WL 1860186, at *5 (D. Del. Feb. 9, 2023). Defendants argue that “the premise of Illumina’s allegation is that the Examiner allowed the claims only after acknowledging she ‘understood the distinction pointed out by Applicant.’” Opp. at 14. But Defendants omit half of the sentence. The summary fully states “Examiner Strzelecka understood the distinction pointed out by Applicant but requested that applicant

³ The issue is not, as Defendants argue, about the truth of Defendants’ claims, but rather their inability to plausibly allege a contradiction between applicants’ statements and Fuller.

distinguish in the claim from the bead-based amplification methods reported in Parameswaran.” Ex. 9 at 4. Defendants’ partial quote stems from an **amendment** made at the examiner’s request to distinguish the pending claims from Parameswaran. In other words, the record shows the patent **was not** granted based on applicant’s statements. The statements thus cannot be but-for material.

3. Defendants’ Theory Of Non-Disclosure For Fuller Fails.

Defendants ignore their failure to plead that Fuller was not cumulative and argue that they did not have to **demonstrate** non-cumulativeness. Opp. at 14-15. But they admit they were required to “identify the claim limitations that [they] believe[] are supposedly absent from the record.” *Id.* Defendants identified no such claim limitation. Their allegation that Fuller contradicts applicants’ statements on Parameswaran is irrelevant to whether Fuller was cumulative of Parameswaran.⁴

Defendants reliance on *Luv n’ Care, Ltd. v. Laurain*, to say that undisclosed references may be non-cumulative if applicant misrepresented scope of other references, is of no moment. The patentee there allegedly misrepresented a characteristic of a prior art device that was not in front of the examiner, not a reference that was squarely in front of the examiner. 98 F.4th 1081, 1097 (Fed. Cir. 2024). In *Luv n’ Care*, the patentee “misrepresented the characteristics of the [m]at by describing it falsely to the PTO (i.e., . . . not practic[ing] self-sealing) and by withholding a video showing that the mat ‘does in fact self-seal to an underlying surface.’” *Id.* Here, by contrast, the Examiner reviewed Parameswaran in detail and applied it in rejections. There were no hidden characteristics for Fuller to disclose beyond the words of Parameswaran. Defendants’ allegations thus fail because they did not and cannot plead Fuller was non-cumulative of Parameswaran.

4. Defendants Cannot Plead Specific Intent.

Defendants misstate the law to save their paltry intent allegations. Defendants claim that

⁴ Defendants argue that Molecular Loop identifies no cumulative reference, but Molecular Loop explained that Fuller’s citation was cumulative of Parameswaran itself. Mot. at 14.

“the question is simply whether Illumina pled ‘underlying facts from which a court may reasonably infer’ that specific individuals knew Fuller was withheld or that Parameswaran was misrepresented.” Opp. at 17. But the law requires “*sufficient allegations of underlying facts* from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a *specific intent to deceive the PTO.*” *Exergen*, 575 F.3d at 1328-29.

Defendants perplexingly argue that they sufficiently pled intent because according to them, a combination of people must have known of Fuller, known Fuller cited Parameswaran, and thus known that applicants’ statements were “false.” Opp. at 17-18. Not only do those allegations lack factual bases, but they do not create a “reasonabl[e] infer[ence] that any individual with knowledge [of a misrepresentation] also had knowledge of the falsity of any material misrepresentation and that the same individual misrepresented the information with a specific intent to deceive the PTO.” *See Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F.Supp.2d 297, 308 (D. Del. 2013).

Defendants also claim Mr. Meyers “affirmatively misrepresented Fuller,” (Opp. at 18 n. 3) but even assuming so, Defendants still cannot allege that anyone “misrepresented this information *with a specific intent to deceive the PTO.*” *Bayer Cropscience AG v. Dow Agrosciences LLC*, 2012 WL 1253047, at *2, *4 (D. Del. Apr. 12, 2012). This Court has dismissed similar claims where defendant alleged a particular person made an affirmative misstatement, but “fail[ed] to plead any facts suggesting [] inten[t] to deceive the PTO.” *Equil*, 722 F.Supp.3d at 456-57.

B. Defendants’ Allegations For The ’730 Patent Fail.

1. Defendants Cannot Plead Materiality.

Defendants admit they cannot plead but-for materiality, arguing instead that for egregious misconduct, “materiality is presumed.” Opp. at 15. But this Court has required some level of materiality even when pleading egregious misconduct. *See Equil*, 722 F.Supp.3d at 454-55. And

despite Defendants' continued attacks on arguments as fact-based, Defendants' allegations *legally* cannot rise to the level of egregious misconduct. Moreover, their attempt to distinguish *Logitech* misreads it. Defendants argue that here, unlike in *Logitech*, there were "multiple false submissions" (Opp. at 17), but the *Logitech* Court did not set an arbitrary rule requiring further affirmative steps to plead egregious misconduct. Instead, the Court dismissed inequitable conduct claims because when Logitech found out there was a question of whether its nonpublication request was proper, "it sought to correct, not take further affirmative steps to prevent discovery." *Universal Elecs. Inc. v. Logitech, Inc.*, 2012 WL 13028549, at *7 (C.D. Cal. Mar. 29, 2012). The same is true here; as soon as Illumina alleged impropriety of the request not to publish, Molecular Loop withdrew it. Mot. at 19. There is no reasonable inference of egregious misconduct here.

2. Defendants Fail To Plead Intent.

Defendants did not plead specific intent to deceive the PTO for the '730 Patent, nor can they. Defendants do not dispute that the PTO had all of the same information Mr. Meyers had, and saw no issue with his request for nonpublication. Mot. at 19-20. Defendants instead resort to the unreasonable position that, even though Mr. Meyers explicitly told the PTO that Application No. 13/266,862 is "a 371 of international" application US 10/01293 (Ex. 16 at 3; Ex. 18 at 3), Mr. Meyers omitted the proper "PCT *label*." Opp. at 20. Defendants cannot plausibly allege that it is deception that arises to outright fraud to identify the relevant statute instead of a "PCT label," especially when the PTO response included the "PCT label." *See* Ex. 15 at 1. Defendants' allegations are "just [] not feasible to argue." *See Attentive Mobile Inc. v. Stodge, Inc.*, No. 1:23-cv-00087, D.I. 385 (D. Del. Sep. 30, 2024) (dismissing inequitable conduct pleadings).

III. CONCLUSION

For the foregoing reasons, Molecular Loop respectfully requests that the Court dismiss Defendants' Counterclaims I-VI and strike Defendants' Seventh-Twelfth Affirmative Defenses.

Dated: December 18, 2024

Respectfully submitted,

OF COUNSEL:

FARNAN LLP

Brian D. Matty
Deborah J. Mariottini
Ashley DaBiere
Kevin Goon
DESMARAIS LLP
230 Park Avenue
New York, NY 10169
Tel: 212-351-3400
Tel: 415-573-1900

/s/ Brian E. Farnan
Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 N. Market St., 12th Floor
Wilmington, DE 19801
(302) 777-0300
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

*Attorneys for Plaintiff Molecular Loop
Biosciences, Inc..*